K092490

STERIS®

NOV - 4 2009

510(k) Summary
For
Amsco Evolution Series Steam Sterilizer
Models HC-2000 and HC-3000

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Contact: Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
Telephone: (440) 392-7695
Fax No: (440) 357-9198

Summary Date: August 12, 2009

Device Name

Trade Name:	Amsco Evolution Series Steam Sterilizer
Models:	HC-2000 and HC-3000
Common/Usual Name:	Steam Sterilizer
Classification Name:	Steam Sterilizer (21 CFR 880.6880, Product Code 80 FLE)

Predicate Devices

K082435, Amsco Evolution Medium Steam Sterilizer (Models HC-600 and HC-1500) cleared December 30, 2008.

K091136, Amsco Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200) cleared June 29, 2009.

Description of Device

The Amsco Evolution Series Steam Sterilizer, Models HC-2000 and HC-3000, are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- *Prevacuum* – is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP)* – is equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The chamber sizes of the proposed Amsco Evolution Series Steam Sterilizer Models are as follows:

- 26" x 61" x 49" (Model HC-2000)
- 26" x 61" x 72" (Model HC-3000)

Intended Use

The Amsco Evolution Series Steam Sterilizer Models HC-2000 and HC-3000 are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- *Prevacuum* – is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP)* – is equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The Amsco Evolution Series *Prevacuum* Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 5-1):

Table 5-1. Amsco Evolution Series *Prevacuum* Steam Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 4-4 for recommended quantities.*
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

*The liquid cycle is for non-patient contact use only.

The Amsco Evolution Series *Steam Flush Pressure-Pulse* (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 5-2):

Table 5-2. Amsco Evolution Series *Steam Flush Pressure-Pulse* (SFPP) Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
SFPP	270°F (132°C)	4 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
SFPP	275°F (135°C)	3 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
SFPP	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 4-4 for recommended quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

*The liquid cycle is for non-patient contact use only.

The following table lists STERIS's recommended loads by sterilizer size:

Table 5-3. Amsco Evolution Series Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 61" x 49" HC-2000	15	40
26" x 61" x 72" HC-3000	25	60

The following table is a guideline for liquid cycle processing:

Table 5-4. Amsco Evolution Series Steam Sterilizer Liquid Cycle Guideline

Number of Containers	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
3	1000 ml	45 minutes

The Amsco Evolution Series Steam Sterilizer is offered in the following chamber sizes:

- 26" x 61" x 49" (Model HC – 2000)
- 26" x 61" x 72" (Model HC – 3000)

Description of Safety and Substantial Equivalence

A summary of the technological characteristics of the device subject of this premarket notification in comparison to those of the predicate devices is included in Table 5-5.

Table 5-5. Summary of the Proposed and predicate Devices
Technological Characteristics

General Sterilizer Features	Amsco Evolution Medium Steam Sterilizer (K091136)	Amsco Evolution Medium Steam Sterilizer (K082435)	Amsco Evolution Series Steam Sterilizer (HC-2000 and HC-3000)
Intended Use	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stable materials in healthcare facilities.	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stable materials in healthcare facilities.	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stable materials in healthcare facilities.
Operating Principle	Steam is the sterilizing agent.	Steam is the sterilizing agent.	Steam is the sterilizing agent
Sterilization Cycles Offered	Prevac Gravity SFPP Liquid	Prevac Gravity SFPP Liquid	Prevac Gravity SFPP Liquid
Chamber Sizes	26" x 26" x 39" 26" x 37.5" x 60"	26" x 37.5" x 42" 26" x 37.5" x 54"	26" x 61" x 49" 26" x 61" x 72"
Chamber Door	Type 316L stainless steel Vertical Sliding (26"x26") Hinged or Horizontal Sliding (26"x37½")	Type 316L stainless steel Vertical Sliding (26"x26") Hinged or Horizontal Sliding (26"x37½")	Type 316L stainless steel Power Horizontal Sliding
Shell Assembly	Type 316L stainless steel ASME certified	Type 316L stainless steel ASME certified	Type 316L stainless steel ASME certified
Control Technology	Unity Controller Touch Screen 8.4" Display Ink on Paper Printer	Unity Controller Touch Screen 8.4" Display Ink on Paper Printer	Unity Controller Touch Screen 8.4" Display Ink of Paper Printer
Process Monitors	Chamber Transducer Dual Element Chamber Drain Sensor	Chamber Transducer Dual Element Chamber Drain Sensor	Chamber Transducer Dual Element Chamber Drain Sensor
Safety Devices	Pressure Relief Valve Chamber Float Switch Control Lockout Switch	Pressure Relief Valve Chamber Float Switch Control Lockout Switch	Pressure Relief Valve Chamber Float Switch Control Lockout Switch

Effectiveness

Effectiveness of sterilizer function and exposure time recommendations was demonstrated by complete kill of biological indicators and by verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} probability of survival. STERIS validates its sterilization cycles using recommended practices, standards and guidelines developed by independent organizations such as the Association for the Advancement of Medical Instrumentation (AAMI). The Amsco Evolution Steam Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8, Fifth Edition, December 2008.

The results of the Amsco Evolution Series Steam Sterilizer validation studies demonstrate that the sterilizer performs as intended. The results are summarized as follows:

- Empty chamber testing performed as described in Section 5.4.2.5 of ANSI/AAMI-ST8, for the Prevac, Gravity, Liquid and SFPP cycles. These cycles demonstrated that the sterilizer is capable of providing steady state thermal conditions within the chamber that are consistent with the predicted sterility assurance level (SAL) in the load. The sterilizer meets the requirements of Sections 4.4.2.2 and 4.4.2.5 of ANSI/AAMI-ST8.
- All SFPP cycles validated using the fabric process challenge device, described in Section 5.5.2.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and no evidence of wet spots.
- All SFPP cycles validated using the wrapped instrument process challenge devices, described in 5.5.4.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.
- All GRAVITY cycles validated using the fabric process challenge device, described in Section 5.5.2.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and no evidence of wet spots.
- All GRAVITY cycles validated using the wrapped instrument process challenge device, described in 5.5.4.1 of ANSI/AAMI-ST8, were qualified according to section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.
- All PREVAC cycles validated using the fabric process challenge device, described in Section 5.5.2.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.
- All PREVAC cycles validated using the wrapped instrument process challenge device, described in 5.5.4.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle analysis, moisture retention of

less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.

- All LIQUID cycles validated using three 1,000 ml flasks, described in Section 5.5.3.1 of the ANSI/AAMI-ST8, and were qualified according to Section 5.5.3 of ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, water loss not exceeding 50 ml, and automatic sealing of the flask closure.
- The DART cycle validated using the Bowie-Dick Test Pack, as described in 5.6.1.1 of the ANSI/AAMI-ST8, was qualified according to Section 5.6.1 of the ANSI/AAMI-ST8, and demonstrated a uniform color change throughout the test sheet.
- The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (05/11/05)."*

Safety

STERIS sterilizers including the Amsco Evolution Steam Sterilizer have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Amsco Evolution Steam Sterilizer complies with the following requirements:

- Underwriters Laboratory (UL) Electrical Safety Code 61010-1 certified by Intertek Testing Services (ITS).
- Canadian Standards Association (CSA) Standard C22.2 No. 61010-1 as certified by Intertek Testing Services.
- Canadian Standards Association (CSA) Standard C22.2 No. 61010-2-040 as certified by Intertek Testing Services.
- American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels.

Hazards – Failure of Performance

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.

To avoid failure, the user must ensure that the materials, instruments and devices to be sterilized are thoroughly cleaned, the manufacturer's instructions for use are followed, the cycle to be used for each type of sterilizer load has been validated, the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

The technology designed into STERIS steam sterilizers including the Amsco Evolution Series Steam Sterilizer provide PC controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

User Information

STERIS conducts in-house training and has developed a series of user training videos that provide helpful information about the appropriate use of steam sterilizers. STERIS further provides information to the user that is intended to ensure safe and effective use of steam sterilization in its detailed Operator Manual and other labeling. STERIS also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in healthcare facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Robert F. Sullivan
Senior Director
Steris Corporation
5960 Heisley Road
Mentor, Ohio 44060

NOV - 4 2009

Re: K092490
Trade/Device Name: The Amsco Evolution Series Steam Sterilizer is offered in the Following Chamber Sizes:
Model HC-2000 36"x61"x49"
Model HC-3000 26"x 61"x72"
Regulation Number: 21CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: August 12, 2009
Received: August 13, 2009

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:
Amsco Evolution Series Steam Sterilizer (HC-2000 and HC-3000)

Indications for Use:

The Amsco Evolution Series Steam Sterilizer Models HC-2000 and HC-3000 are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- *Prevacuum* – is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP)* – is equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The Amsco Evolution Series *Prevacuum* Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4-1):

Table 4-1. Amsco Evolution Series *Prevacuum* Steam Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time*	Recommended Load
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 4-4 for recommended quantities.*
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Gravity	270°F (132°C)	15 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

*The liquid cycle is for non-patient contact use only.

The Amsco Evolution Series *Steam Flush Pressure-Pulse* (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 4-2):

Table 4-2. Amsco Evolution Series *Steam Flush Pressure-Pulse* (SFPP) Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
SFPP	270°F (132°C)	4 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
SFPP	275°F (135°C)	3 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 for recommended quantities.*
SFPP	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	45 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 4-4 for recommended quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

*The liquid cycle is for non-patient contact use only.

The following table lists STERIS's recommended loads by sterilizer size:

Table 4-3. Amsco Evolution Series Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 61" x 49" HC-2000	15	40
26" x 61" x 72" HC-3000	25	60

The following table is a guideline for liquid cycle processing:

Table 4-4. Amsco Evolution Series Steam Sterilizer Liquid Cycle Guideline

Number of Containers	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
3	1000 ml	45 minutes

The Amsco Evolution Series Steam Sterilizer is offered in the following chamber sizes:

- Model HC – 2000 26" x 61" x 49"
- Model HC – 3000 26" x 61" x 72"

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Claussi - Wells
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092490